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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NC
09/535,300	03/24/00	SCHWABACHER A	2003118-00

HM12/1023

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EXAMINER	
GARCIA,M	

ART UNIT	PAPER NUMBEI
1627	9

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceedi

Commissioner of Patents and Tradema

PTO-90C (Rev.11/00)

1- File Copy

File Copy

Office Action Summary	Application No. 09/535,300	Applicant(s) Schwabacher et al
	Examiner Maurie E. Garcia, Ph. D.	Art Unit 1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 6, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the applica

4a) Of the above, claim(s) *2, 5, 9, 12, and 14-29* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3, 4, 6-8, 10, 11, and 13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The Response filed August 6, 2001 (Paper No. 7) is acknowledged. No claims were amended, added or cancelled. Therefore, claims 1-29 are pending.

Election/Restriction

2. Applicant's election of Group II (claims 1 (in part), 3, 4, and 6-13) is acknowledged as well as the election of species (Species of cladding: sol-gel and Species of derivative: aminopropylsilyl).

3. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Thus, claims 2, 5 and 14-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Election was made **without** traverse in Paper No. 7 (see paragraph 3 above).

5. Also, claims 9 and 12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

6. Therefore, claims 1, 3, 4 and 6-13 are examined on the merits in this action.

Priority

7. Applicant's claim for domestic priority under 35 U.S.C. 120 and 119(e) is acknowledged. The instant application is a continuation-in-part of 09/253,153, which claims priority to provisional application 60/075,629. However, priority has ***not*** been granted to all of the instant claims, as described in detail below.

8. The co-pending parent application (09/253,153) only supports the general concept of making a spatially defined array on an optical fiber (see page 14, line 20 through page 15, line 2 of that application) but not the specifics set forth in the instant claims 7, 8, 11 and 13. Note that 09/253,153 does not mention any cladding material or the specific derivatization agent in instant claim 11. A broad generic disclosure is **not** sufficient support for a specific entity within the class.

9. Also, applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e). Provisional application 60/075,629, upon which priority is claimed, fails to provide adequate support under 35 U.S.C. 112 for the claims of the instant application since it does not contain **any** reference to creating arrays on an optical fiber.

10. Thus, the claims have been awarded filing dates as follows:

Claims 1, 3, 4, 6 and 10 are granted the filing date of 09/253,153, which is February 19, 1999.

Claims 7, 8, 11 and 13 are only granted the filing date of the instant application, which is March 24, 2000.

Information Disclosure Statement

11. The information disclosure statement filed August 31, 2000 fails to fully comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein for the Khijwania et al and Lockhart et al references has not been considered, as copies of these two references could not be found in the file.

Drawings

12. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. The drawings are objected to by the draftsperson under 37 C.F.R. 1.84 or 1.52. See PTO-948 for the details of these objections. Correction of the noted defects in the drawings can only be deferred until the application is allowed by the examiner.

13. For Figure 16 in the instant case, the Brief Description of the Drawings is incomplete. The specification refers only to Figure 16, while the drawings show Figures 16a) and 16b). A Brief Description is necessary for each view.

See 37 CFR 1.74:

> When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures and to the different parts by use of reference letters or numerals (preferably the latter).

Appropriate correction is required.

Specification

14. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 7, line 17). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 6-8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Browne et al (Anal. Chem. 1996; on PTO-1449).

Browne et al disclose an "intrinsic sol-gel clad fiber optic sensor" (see Title and Abstract) which reads on the claimed array of agents attached to an optical fiber as set forth below. The reference discloses that the "active sensor region of a fiber can be either immobilized at the distal end of an optical fiber (extrinsic) or distributed along the length of the fiber-optic waveguide (intrinsic)" (page 2289, 1st column, bottom). Specifically, Browne et al disclose a sol-gel clad optical fiber (see page 2291; Figure 1 and 1st column under 'Experimental Section; Sol-Gel Matrix'). Note that the claddings were "applied by dip-coating silica core fibers". This reads on the limitations of instant claims 7, 8 and 13.

The above-described fibers of Browne et al have sol-gel clad *regions* of the fiber that are created by removing the cladding from a silicone clad fiber and then replacing it with sol-gel cladding in the regions where the silicone was removed (see page 2291 1st column under 'Experimental Section; Sol-Gel Clad Fiber'). Several different dyes were used as dopants in the sol-gel regions; these dyes read on the claimed "array of agents attached to an optical fiber". Browne's purposely created *regions* of sol-gel clad fiber correspond to the claimed "pre-determined portion of the optical fiber" and "reactant regions" of instant claims 1 and 6. The fiber shown on page 2292 of the reference (in Figure 3 and discussed under section denoted (b)) reads specifically on the claimed array of agents as it shows a fiber that has four regions with attached AA and CV dyes that are spatially resolved.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1, 6-8, 10, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browne et al, as set forth above, in view of Pilevar et al (Anal. Chem. 1998; on PTO-1449).

Browne et al teach an "intrinsic sol-gel clad fiber optic sensor" (see Title and Abstract) which reads on the claimed array of agents attached to an optical fiber as set forth below. The reference teaches that the "active sensor region of a fiber can be either immobilized at the distal end of an optical fiber (extrinsic) or

distributed along the length of the fiber-optic waveguide (intrinsic)" (page 2289, 1st column, bottom). Specifically, Browne et al teach a sol-gel clad optical fiber (see page 2291; Figure 1 and 1st column under 'Experimental Section; Sol-Gel Matrix'). Note that the claddings were "applied by dip-coating silica core fibers". This reads on the limitations of instant claims 7, 8 and 13.

The above-described fibers of Browne et al have sol-gel clad *regions* of the fiber that are created by removing the cladding from a silicone clad fiber and then replacing it with sol-gel cladding in the regions where the silicone was removed (see page 2291 1st column under 'Experimental Section; Sol-Gel Clad Fiber'). Several different dyes were used as dopants in the sol-gel regions; these dyes read on the claimed "array of agents attached to an optical fiber". Browne's purposely created *regions* of sol-gel clad fiber correspond to the claimed "pre-determined portion of the optical fiber" and "reactant regions" of instant claims 1 and 6. The fiber shown on page 2292 of the reference (in Figure 3 and discussed under section denoted (b)) reads specifically on the claimed array of agents as it shows a fiber that has four regions with attached AA and CV dyes that are spatially resolved.

Browne et al lacks the teaching of the limitations of claims 10 and 11 with respect to derivatization and aminopropylsilylation.

However, it was well known in the art at the time of filing that optical fibers can be derivatized with a variety of agents and that aminopropylsilylation was a common method of performing such processes. Browne et al lists several

different analytes that have been used in fiber-optic chemical sensors (see page 2289, 2nd column, last paragraph). The use of aminopropylsilane provides a surface with amino groups thereon for further functionalization. Pilevar et al specifically teach the attachment of fluorophores to an optical fiber through the use of derivatization of the fiber with aminopropylsilane (see 'Chemical Treatment of Fiber Optic Surface' on page 2033 of the reference).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to derivatize the fibers of Browne et al by the use of aminopropylsilane based on the teachings of Pilevar et al directed towards the use of such agents to derivatize optical fibers. One would have been motivated to do so because Browne et al teach that intrinsic chemical sensors having agents that are "macroscopically distributed along a single optical fiber" are suited for certain specific sensing applications (see Browne et al, page 2292, (b)). That is, one of ordinary skill would contemplate making the fibers of Browne et al by using aminopropylsilane derivatization to obtain arrays that have a variety of groups attached thereto having improved properties for specific sensing applications.

20. Claims 1, 3, 4, 6-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browne et al, as set forth above, and further in view of Pirrung et al (US 5,143,854; on PTO-1449).

Browne et al teach an "intrinsic sol-gel clad fiber optic sensor" (see Title and Abstract) which reads on the claimed array of agents attached to an optical fiber as set forth below. The reference teaches that the "active sensor region of a fiber can be either immobilized at the distal end of an optical fiber (extrinsic) or distributed along the length of the fiber-optic waveguide (intrinsic)" (page 2289, 1st column, bottom). Specifically, Browne et al teach a sol-gel clad optical fiber (see page 2291; Figure 1 and 1st column under 'Experimental Section; Sol-Gel Matrix'). Note that the claddings were "applied by dip-coating silica core fibers". This reads on the limitations of instant claims 7, 8 and 13.

The above-described fibers of Browne et al have sol-gel clad *regions* of the fiber that are created by removing the cladding from a silicone clad fiber and then replacing it with sol-gel cladding in the regions where the silicone was removed (see page 2291 1st column under 'Experimental Section; Sol-Gel Clad Fiber'). Several different dyes were used as dopants in the sol-gel regions; these dyes read on the claimed "array of agents attached to an optical fiber". Browne's purposely created *regions* of sol-gel clad fiber correspond to the claimed "pre-determined portion of the optical fiber" and "reactant regions" of instant claims 1 and 6. The fiber shown on page 2292 of the reference (in Figure 3 and discussed under section denoted (b)) reads specifically on the claimed array of agents as it shows a fiber that has four regions with attached AA and CV dyes that are spatially resolved.

Browne et al lacks the teaching of the limitations of claims 3 and 4 with respect to specifically using peptides or proteins as the agent that is attached to the fiber.

However, it was well known in the art at the time of filing that optical fibers can be derivatized with a variety of agents. Browne et al lists "biological analytes" and specifically antibodies that can be used in fiber-optic chemical sensors. Moreover, it was also well known in the art to make arrays of peptides/proteins on a solid support in order to have a large number of sequences to conveniently screen. Pirrung et al teach the creation of arrays by "placement of materials at known locations" (column 1, line 28) and discuss the use of peptides and proteins as the materials of the array (column 1, line 32 through column 2, line 14 & column 28, lines 5-11, for example). Pirrung et al specifically teach that their arrays can be synthesized using optical fibers as a support (column 14, lines 55-59). Pirrung et al also use fluorescent markers to identify reactive members of the array (see column 3, lines 45-49 & column 28, lines 50-59, for example).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the fibers of Browne et al as a support for an array of peptides or proteins based on the teachings of Pirrung directed towards the use of optical fibers as supports for their arrays and the use of fluorescent markers. One would have been motivated to do so because Browne et al teach that intrinsic chemical sensors having agents that are "macroscopically

distributed along a single optical fiber" are suited for certain specific sensing applications (see Browne et al, page 2292, (b)). Also, the fibers of Browne et al are specifically used to measure fluorescence. That is, one of ordinary skill would contemplate making the fibers of Browne et al with attached peptides or proteins to obtain arrays with improved properties for specific sensing applications and to be able to have a method to easily detect fluorescent markers. Moreover, one of ordinary skill would be motivated to create large arrays of peptides or proteins to screen for biological activity (see Pirrung et al column 3, lines 35-61).

Status of Claims/Conclusion

21. No claims are allowed.

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Adams et al (US 6,156,494) teaches using functionalized optical fibers as a support for combinatorial libraries of compounds. The individual library compounds are each made in a separate region, i.e. on a different fiber of a fiber bundle. See Abstract; Figure 1; column 2, line 59 through column 3, line 4 & column 4, lines 1-40.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703)

308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
October 19, 2001

MAURIE E. GARCIA, Ph.D
PATENT EXAMINER